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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/495,668	02/01/2000	Sergey A. Selifonov	3271.002US1	5158

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EXAMINER

KIM, YOUNG J

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 12/31/2001

19

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/495,668	Applicant(s) SELIFONOV ET AL.	
	Examiner Young J. Kim	Art Unit 1631	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-44 is/are pending in the application.  
     4a) Of the above claim(s) 31-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
     a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>18</u> . | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1-30 in Paper No. 17 is acknowledged. The traversal is on the ground(s) that the inventions of the instant application have been already examined. This is not found persuasive because as already set forth in the previous Office Action, the restriction practice could occur at any time during the prosecution of the application at the discretion of the Examiner. Upon careful reconsideration of the application, the inventions have been properly restricted.

The requirement is still deemed proper and is therefore made FINAL.

Claims 31-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 17.

### ***Information Disclosure Statement***

The Information Disclosure Statement received on July 2, 2001 (Paper No. 13) and the references listed therein have not been considered because the references received by the PTO did not correspond with the references listed in the IDS. It appears that the references received correspond to another related application. The IDS received on December 7, 2001 (Paper No. 18) and the references listed therein have been considered and the signed copy of the IDS is attached hereto.

Finally, in response to the Applicants' statement regarding the IDS sent on August 11, 2001 not being considered, it appears that due to the error in the PTO, the references have been

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lost. In regards to the Applicants' statement indicating that returned postcard being attached to their response, none had been attached. Applicants are asked to call the Examiner of record before sending the references to have them directly delivered.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 10, 14, 22, and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is indefinite for the recitation of the phrase, "amino acid sequences comprise a nucleic acid sequence encoding a known protein," because an amino acid sequence cannot comprise a nucleic acid sequence (it is either or). Further, the claim is indefinite for the recitation of the term "known" because it becomes unclear when the protein is "known," (i.e., at the time of the filing of the application or later).

Claims 10 and 22 are indefinite for the recitation of the phrase, "selecting a character that is a member of an aligned pair for the end of one substring," because it is unclear whether the term "aligned pair" refers to the aligned two initial character strings or another aligned pair. For the purpose of prosecution, the term is assumed to refer to the aligned two initial character strings.

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Claim 14 recites the limitation "said coding." There is insufficient antecedent basis for this limitation in the claim. Amending the claim to recite "said encoding" would overcome this rejection.

Claim 30 recites the limitation "said code." There is insufficient antecedent basis for this limitation in the claim. Amending the claim to recite "said computer code" would overcome this rejection.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 17-30 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn to a computer program product. A computer program product must be on a computer readable media for it to be statutory subject matter. Amending the claims to recite, "a computer program product on a computer readable media" would overcome this rejection.

Claims 1-30 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

Definitions: [from REVISED INTERIM UTILITY GUIDELINES TRAINING

MATERIALS; repeated from <http://www.uspto.gov/web/menu/utility.pdf>]

"Substantial utility" - a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a "substantial utility" define a "real world" context of use. An assay that measures the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a "real world" context of use in identifying potential candidates for preventive measures or further monitoring. On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

A. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved.

B. A method of treating an unspecified disease or condition. (Note, this is in contrast to the general rule that treatments of specific diseases or conditions meet the criteria of 35 U.S.C. § 101.)

C. A Method of assaying for or identifying a material that itself has no "specific and/or substantial utility".

D. A method of making a material that itself has no specific, substantial, and credible utility.

E. A claim to an intermediate product for use in making a final product that has no specific, substantial, and credible utility.

Note that "throw away" utilities do not meet the tests for a *specific* or *substantial* utility. For example, using transgenic mice as snake food is a utility that is neither specific (all mice could function as snake food) nor substantial (using a mouse costing tens of thousands of dollars to produce as snake food is not a "real world" context of use). Similarly, use of any protein as an animal food supplement or a shampoo ingredient are "throw away" utilities that would not pass muster as specific or substantial utilities under 35 U.S.C. § 101. This analysis should, of course, be tempered by consideration of the context and nature of the invention. For example, if a transgenic mouse was generated with the specific provision of an enhanced nutrient profile, and disclosed for use as an animal food, then the test for specific and substantial *asserted* utility would be considered to be met.

"Well established utility" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. "Well established utility" does not encompass any "throw away" utility that one can dream up for an invention or a nonspecific utility that would apply to virtually every member of a general class of materials, such as proteins or DNA. If this is the case, any product or apparatus, including perpetual motion machines, would have a "well established utility" as landfill, an amusement device, a toy, or a paper weight; any carbon containing molecule would have a "well established utility" as a fuel since it can be

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burned; any protein would have well established utility as a protein supplement for animal food. This is not the intention of the statute.

[See also the MPEP at §§ 2107 - 2107.02].

The claimed method lacks patentable utility because the claimed method does not render itself useful to a skilled artisan for “real-world” application. The background of the invention in the specification states that there exists, “an extensive history of the use of computers to simulate and/or investigate the evolution of life, of individual genetic systems and/or population genetic/phenotypic systems” (lines 13-15, pp. 1). In the Summary of the Invention, the specification states that the, “invention provides novel methods of generating “initial populations suitable for further computational manipulation, e.g. via genetic/evolutionary algorithms” (lines 17-20, pp. 3). Clearly, this method falls under the subtype (A) of the Utility Guidelines, that is, a research tool to further research the products produced by the claimed methods. The products, produced by the claimed methods would result in a population of randomly concatenated nucleic acid or amino acid sequences wherein its practical usage, other than conducting further research, would not be recognized by a skilled artisan. Although the claimed method could be used to narrow the field of empirically determining which of the produced recombined nucleic acids would be further analyzed, the immediate use of the recombined nucleic acids are evident other than the need for further research, rendering the claimed methods and program comprising the method lacking in a “real-world” utility (i.e., does not produce a tangible useful product).

The population of the randomly concatenated nucleic acids or amino acid sequences would necessitate a skilled artisan to conduct further research to verify its “usefulness” for real-world application. A program product on a computer readable medium comprising the methods

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would also lack patentable utility because the method performed by the program product, as stated above, lacks patentable utility.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-30 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

#### ***Claim Rejections - 35 USC § 102***

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-5, 12-13, 14-17, 24-25, and 26-27 rejected under 35 U.S.C. 102(a) as being anticipated by Sun (Journal of Computational Biology, 1999).

Claims are drawn to a method (program enabling the method) of populating a data structure with a plurality of character strings which involves encoding a population of nucleic acid or amino acid into character strings and to select regions within the character strings (substrings) which meet various selection criteria for concatenation (or recombination in computer model). Claims are also drawn to a computer program product comprising a computer code that achieves the above methods.

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Sun reference teaches a computerized model of DNA shuffling (pp. 77 for general teachings) which involves computer simulated acts of annealing, extension reactions of random fragments that is, effect, "concatenations of random fragments" (pp. 79-81, 86 (second paragraph), and 88 (last paragraph) specifically 81).

Various selection criteria which must be considered for such recombination to occur is disclosed by Sun (pp. 79-80).

Sun reference disclose that a compute algorithm has been developed to simulate the shuffling process (pp. 86) demonstrating that the program on a computer readable media executed the recited method.

Therefore, Sun anticipates the invention as claimed.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun (Journal of Computational Biology, 1999).

Claims are drawn to a method of populating a data structure with a plurality of character strings which involves encoding a population of nucleic acid or amino acid into character strings and to select regions within the character strings (substrings) which meet various selection criteria for concatenation (or recombination in computer model). Some embodiments are drawn to various percent sequence identity selection criteria. Some embodiment is drawn to alteration of at least one base (or a character within a character string). Claims are also drawn to a computer program product comprising a computer code that achieves the above methods.

Sun reference teaches a computerized model of DNA shuffling (pp. 77 for general teachings) which involves computer simulated acts of annealing, extension reactions of random fragments that is, effect, "concatenations of random fragments" (pp. 79-81, 86 (second paragraph), and 88 (last paragraph) specifically 81).

Various selection criteria which must be considered for such recombination to occur is disclosed by Sun (pp. 79-80).

Sun reference disclose that a compute algorithm has been developed to simulate the shuffling process (pp. 86) demonstrating that the program on a computer readable media executed the recited method.

Sun does not specifically teach a selection criteria requiring specific percent identity of greater than 30% as required by claims 11 and 23 fragment selection criteria.

Sun does not specifically teach mutating (or changing a character within a character string).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have use the teachings of Sun by modifying specific selection criteria well within the purview of a skilled artisan to arrive at the invention as claimed.

One of ordinary skill in the art would have been motivated to do so for the following reasons.

Sun discloses a motivation to generate a population (or a library) of random molecules such as DNA, RNA, or protein (pp. 77), that is, to evolve molecules with desired properties.

Sun, however, discloses that a, “completely random library may not be good choice as any library can contain only a very small fraction of the potential molecule... Instead, a library generated through mutagenesis from one or a few molecules already known to have some desired property might be more useful” (pp. 77). Sun goes on to disclose that, “Mutagenesis is one important step in in vitro evolution experiments. It can be used to generate the initial random molecule library... In this paper we consider one important mutagenesis method called DNA shuffling” (pp. 78, 1<sup>st</sup> paragraph).

Sun discloses a computation model of DNA shuffling and selection criteria such as probability factor of targets being reassembled (or concatenated as the claims read) (pp. 80-85). Although no specific numbers are mentioned by Sun in determining selection criteria, it is assumed from both the teachings of Sun and the knowledge of an ordinarily skilled artisan in the art of bioinformatics, arriving at such criteria is empirical through use of the disclosed program of Sun.

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Therefore, an ordinarily skilled artisan would have been motivated to use the disclosure of Sun to arrive at the claimed method of populating data structure (or generation of library via DNA shuffling).

*Double Patenting*

Claims 1-30 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that claims 1-30 of copending Application SN: 09/724,758. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

No claim is allowed.

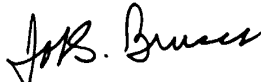
*Inquiries*

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (703) 308-9348. The Examiner can normally be reached from 8:30 a.m. to 7:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028. Papers related to this application may be submitted to Art Unit 1631 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. The Fax number is (703) 746-3172. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Young J. Kim

12/29/01



  
JOHN S. BRUSCA, PH.D  
PRIMARY EXAMINER